

THOMAS BOWLEN,

Plaintiff,

v.

**COLOPLAST A/S, COLOPLAST
MANUFACTURING, US, LLC,
COLOPLAST CORPORATION, and
COLOPLAST INTERNATIONAL, LLC,**

Defendants.

**COLOPLAST A/S, COLOPLAST)
MANUFACTURING, US, LLC,)
COLOPLAST CORPORATION, and)
COLOPLAST INTERNATIONAL, LLC,)
)
Defendants.)**

Thomas Bowlen (“plaintiff”) commenced this action against Coloplast A/S; Coloplast Manufacturing US, LLC; Coloplast Corporation; and Coloplast International, LLC (“defendants”) asserting claims for negligence, strict liability, and breach of express warranties. Presently before the court is defendants’ motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). For the reasons set forth below, defendants’ motion will be granted in part and denied in part.

It is well-settled that in reviewing a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) "[t]he applicable standard of review requires the court to accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the non-moving party." Rocks v. City of Philadelphia, 868 F.2d 644, 645 (3d Cir. 1989). Under the Supreme Court's decision in Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 561 (2007), dismissal of a complaint pursuant to Rule 12(b)(6) is proper only where the averments of the complaint plausibly fail to raise directly or inferentially

the material elements necessary to obtain relief under a viable legal theory of recovery. Id. at 544. In other words, the allegations of the complaint must be grounded in enough of a factual basis to move the claim from the realm of mere possibility to one that shows entitlement by presenting "a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 570).

"A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. In contrast, pleading facts that only offer "'labels or conclusions' or 'a formulaic recitation of the elements of a cause of action will not do,'" nor will advancing only factual allegations that are "'merely consistent with' a defendant's liability." Id. Similarly, tendering only "naked assertions" that are devoid of "further factual enhancement" falls short of presenting sufficient factual content to permit an inference that what has been presented is more than a mere possibility of misconduct. Id. at 1949-50; see also Twombly, 550 U.S. at 563 n. 8 (A complaint states a claim where its factual averments sufficiently raise a "'reasonably founded hope that the [discovery] process will reveal relevant evidence' to support the claim.") (quoting Dura Pharmaceuticals, Inc. v. Broudo, 544 U.S. 336, 347 (2005) & Blue Chip Stamps v. Manor Drug Stores, 421 U.S. 723, 741 (1975)); accord Morse v. Lower Merion School Dist., 132 F.3d 902, 906 (3d Cir. 1997) (a court need not credit "bald assertions" or "legal conclusions" in assessing a motion to dismiss) (citing with approval Charles Alan Wright & Arthur R. Miller, FEDERAL PRACTICE AND PROCEDURE § 1357 (2d ed. 1997) ("courts, when examining 12(b)(6) motions, have rejected 'legal conclusions,' 'unsupported conclusions,' 'unwarranted inferences,' 'unwarranted deductions,' 'footless conclusions of law,' or 'sweeping legal conclusions cast in the form of factual allegations.'").

This is not to be understood as imposing a probability standard at the pleading stage. Iqbal, 556 U.S. at 678 ("The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully."); Phillips v. County of Allegheny, 515 F.3d 224, 235 (3d Cir. 2008) (same). Instead, "[t]he Supreme Court's Twombly formulation of the pleading standard can be summed up thus: 'stating ... a claim requires a complaint with enough factual matter (taken as true) to suggest the required element ... [and provides] enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element.'" Phillips, 515 F.3d at 235; see also Wilkerson v. New Media Technology Charter School Inc., 522 F.3d 315, 321 (3d Cir. 2008) ("The complaint must state 'enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element.'" (quoting Phillips, 515 F.3d at 235) (citations omitted). "Once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." Twombly, 550 U.S. at 563.

The facts read in the light most favorable to plaintiff are as follows. On May 6, 2015 plaintiff underwent a surgical procedure performed by Dr. Thomas Jaffee at UPMC Magee Women's Hospital. The procedure was to implant defendants' Titan penile implant device ("Titan") into plaintiff to help treat his erectile dysfunction. The Titan was advertised as a device that would replicate the "look and performance of a natural erection." Defendants also represented that the Titan was safe for its intended purpose and would not fail during normal use.

The Titan consists of two cylinders and a pump/deflate valve mechanism. The reservoir, which is placed in the abdomen, contains fluid. The fluid from the reservoir fills and empties the two cylinders within the shaft of the penis to inflate and deflate, giving the effect of a natural erection. The pump, which controls the inflation and deflation, is placed in the scrotum. To

inflate, the user must squeeze the pump which forces the fluid into the cylinders. To deflate, the user must squeeze a valve on top of the pump which releases the fluid out of the cylinders.

After the procedure Dr. Jaffee kept the cylinders partially inflated so plaintiff could heal correctly. Plaintiff was discharged from the hospital and followed all of Dr. Jaffee's instructions in order to heal properly. Plaintiff deflated the cylinders as instructed. After deflating the cylinders, however, his Titan would automatically and fully re-inflate.

The Titan was designed with a lock-out valve that was meant to prevent auto-inflation. It failed in this situation. The cylinders were not meant to be inflated fully directly after surgery. Each time that re-inflation occurred, plaintiff experienced constant and severe pain because he had not fully healed. Additionally, deflating would also cause severe pain. After the deflation, plaintiff would experience temporary relief but then would experience an urgent need to urinate. This state of affairs continued for two and a half months.

On July 14, 2015, Dr. Jaffee recommended performing another surgery to either repair or replace the Titan. Without the surgery, plaintiff would continue to suffer pain for an indefinite period of time. The procedure occurred on July 27, 2015. During the procedure Dr. Jaffee discovered that the pump unit was defective in that it took a "tremendous amount of force" to deflate the cylinders. Upon discovering this, Dr. Jaffee replaced the defective pump with a new one. Although the new pump required less force and was easier to compress, plaintiff has continued to experience auto-inflation. As a result, he has suffered 1) a loss of earning capacity and lost wages, 2) extreme pain, 3) scarring, 4) disfigurement, 5) unexpected medical expenses, and 6) a diminished ability to enjoy various pleasures of life. He also has difficulty urinating while standing up because his penis is now curved to the right.

Defendants advance three reasons in support of their motion to dismiss. First, the state-law claims of negligence and strict liability purportedly are preempted by the express preemption provision in the Medical Device Amendment (“MDA”), 21 U.S.C. § 301. Second, the state-law claim of strict liability fails as a matter of Pennsylvania law based on comment k in the Restatement (Second) of Torts § 402A to the extent the claim is premised on allegations of a design defect. Finally, defendant asserts plaintiff has failed to allege sufficient facts to state a plausible claim for breach of express warranties.

Plaintiff contends his state-law claims of negligence and strict liability are not barred because they fall within an exception to the MDA’s preemption provision. Similarly, his strict liability claim is not precluded by comment k. Finally, he asserts that his complaint has alleged sufficient facts to state a plausible claim for breach of express warranties.

Plaintiff’s strict liability and negligence claims are not preempted by the MDA. The MDA was enacted to oversee and control the safety and effectiveness of medical devices being introduced into the marketplace. Medtronic, Inc. v. Lohr, 518 U.S. 470, 476 (1996). It separates medical devices into three classes. Id. The classification of a device will depend on the risks that it poses to the public. Id. The class that a device falls into will determine the amount of oversight needed to obtain FDA approval. Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008).

Class I devices “present no unreasonable risk of illness or injury.” Lohr, 518 U.S. at 476-77. This class is subject to “minimal regulation by ‘general control.’” Id. at 477 (quoting 21 U.S.C. 360c(a)(1)(A)). Class II devices are those that are “potentially more harmful.” Id. at 477. Devices that fall into this class “must comply with federal performance regulations known as ‘special controls.’” Id. at 477. Class III devices are those that are used for “supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of

human health.” 21 U.S.C. § 360c(a)(1)(C). A device also is placed in Class III if it “presents a potential unreasonable risk of illness or injury.” Id.

Class III devices require the most oversight. Riegel, 522 U.S. at 316-17. Manufacturers of these devices must provide “reasonable assurances” to the Food and Drug Administration (“FDA”) about the device’s safety and effectiveness. Lohr, 518 U.S. at 477 (quoting 21 U.S.C. 360e). As part of this process the manufacturer must obtain premarket approval (“PMA”) for the device before it is released to the public. Id.

The process to obtain PMA “is a rigorous one.” Id. at 477. It requires manufacturers to “submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews.” Id. A review of each submission, on average, takes about 1,200 hours. Id.

In exchange for complying with these requirements, Class III devices are afforded express preemption. Shuker v. Smith & Nephew, PLC, 885 F.3d 760, 764 (3d Cir. 2018). The preemption provision states:

No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human life use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device

21 U.S.C. 360k(a).

Riegel established a two-step framework to determine if a medical device is preempted under the MDA. 522 U.S. at 321. First, it must be determined whether the federal government has established applicable requirements for the device. Id. Once a device has obtained PMA, the FDA then requires that manufacturers produce the device in a manner that does not deviate from the “specifications in its approval application.” Id. at 322. These FDA specifications are considered the applicable requirements to a device because they “impose[s] ‘requirements’ under

the MDA” onto the manufacturers. When this occurs, obtaining PMA satisfies the first part of the test. Id.

If the FDA has established applicable requirements to the device, the next determination is whether the common-law claims are based upon state “requirements with respect to the device that are ‘different from, or in addition to,’ the federal ones, and that relate to safety and effectiveness.” Id. at 321-22 (quoting 21 U.S.C. § 360k(a)). As a general matter, the state-law claims of “negligence and strict liability do impose [such] ‘requirement[s]’ and [are] pre-empted.” Id. at 323. However, claims of this nature that “‘parallel,’ rather than add to [the] federal requirements” are not. Id. at 330.

Parallel claims are “claims premised on state requirements that merely incorporate applicable federal requirements and therefore are not ‘different from, or in addition to,’ federal requirements.” Shuker, 885 F.3d at 768 (quoting Lohr, 518 U.S. at 494-95). A parallel negligence claim would be limited to “(1) a duty arising from federal requirements applicable to a medical device, (2) a breach of that duty, and (3) a causal connection between the breach and the [plaintiff’s] injuries.” Shuker, 885 F.3d at 776. To bring a parallel strict liability claim, it is not enough for the device simply to have stopped working. Williams v. Cyberonic, Inc., 388 Fed. Appx. 169, 171-72 (3d Cir. 2010). Instead, a plaintiff needs to explain how the medical device deviated from the FDA requirements. Williams, 388 Fed. Appx. at 171.¹

The Third Circuit likewise has not determined how specific a plaintiff must be at the pleading stage with regard to the federal requirements a defendant has violated. Some district

¹ The Third Circuit has not directly determined what is required to plead a claim of strict liability. The strict liability claim before the court in Williams was reviewed at summary judgement.

courts have dismissed claims for failure to specify how a defendant violated the FDA requirements. See McLaughlin v. Bayer Corporation, 172 F.Supp.3d 804, 816-18, 839-40 (E.D. Pa. 2016) (dismissing negligence claims that failed to specify how the defendant deviated from FDA requirements); Starks v. Coloplast Corp., 2014 WL 617130 (E.D. Pa. 2014) (dismissing both negligence and strict liability claims because allegations were too general); Gross v. Stryker Corp., 858 F.Supp.2d 466, 494 (W.D. Pa. 2012) (“broad references to federal regulations are insufficient to establish the duty element of a negligence state law claim which would parallel a violation of federal law”).

Other courts have examined more closely the inherent difficulty in demanding such precision at the pleading stage. In Killen v. Stryker Spine, 2012 WL 4498865 (W.D. Pa. Sept. 28, 2012), Chief Judge Conti noted that an issue can arise for a plaintiff during the pleading stage. In order to be sufficiently pled and satisfy the parallel claim exception, a plaintiff must identify how the defendant breached the FDA requirements. Id. at *2. But the information to do this typically is held exclusively by the defendant and the FDA. Id. *3. It would be overly demanding to insist that a plaintiff plead the specific requirements giving rise to the parallel claim exception but foreclose the only opportunity a plaintiff has to identify and then prove the exception. Id. (citing to Hofts v. Howmedica Osteonics Corp., 597 F.Supp.2d 830, 838 (S.D. Ind. 2009); Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010)). Therefore, if a plaintiff has not had access the information which would otherwise permit the plaintiff to state more specifically which FDA regulations a defendant has violated, the pleading standard will be deemed satisfied if the plaintiff has alleged sufficient facts “that plausibly suggest the existence of parallel claims.” Id.

Here, it is undisputed that the Titan is a Class III device that was required to go through the PMA process. As a result of that process the FDA put in place particular requirements that defendants must follow when manufacturing it. Obtaining PMA status is sufficient to satisfy the first part of the preemption test.

Defendants' efforts to establish the second part of the test falls short of the mark. The allegations here are based on defendants' failure to meet the FDA requirements. In other words, plaintiff does not attempt to impose requirements that are different from or in addition to the federal requirements; to the contrary, he merely avers that the product was not produced in accordance with the authorized protocol implemented to make it function as intended. Moreover, plaintiff only has had access to the documents that indicate defendants obtained PMA status. He has not had access to the PMA itself, which would include the federal requirements defendants must abide by when manufacturing the Titan. Without the PMA it would be impossible to state with any level of detail what federal requirements defendants violated.

Nevertheless, plaintiff has alleged sufficient facts that plausibly suggest the existence of parallel claims. The Titan went through the rigorous process of obtaining PMA status. Obtaining that status means that the FDA determined that the Titan was safe for public use and put procedures in place to ensure this.

The Titan that was implanted into plaintiff did not work properly. This is evident by the fact that the Titan specifically was designed to prevent auto-inflation and yet plaintiff's device would auto-inflate and cause severe and constant pain. Additionally, when the product was removed the doctor noted that it took a tremendous amount of force to deflate the cylinders. Plaintiff asserts in his complaint that his Titan was manufactured in a way that caused the device to malfunction. Given the rigorous protocol presumably produced from the PMA approval

process, these factual allegations provide a plausible basis to infer that defendants failed to follow procedures put in place by the FDA. Therefore, because plaintiff's strict liability and negligence claims fall into the parallel claim exception they are not preempted.²

Plaintiff likewise has averred sufficient facts to state a plausible claim for breach of express warranty. To succeed on a breach of express warranty claim a plaintiff must show "(1) defendants breached or failed to meet its warranty promise, (2) the breach was the proximate cause of the harm, and (3) there were ensuing damages." Stevens v. C.R. Bard, Inc., 2018 WL 692097 (W.D. Pa. 2018) (citing Samuel-Bassett v. Kia Motors America, Inc., 34 A.3d 1, 35 (Pa. 2011)).

An express warranty is "some form of promise or affirmative statement." McPhee v. Depuy Orthopedics, Inc., 989 F. Supp.2d 451, 466 (W.D. Pa. 2012). It can be created by any 1) "affirmation of fact or promise made by the seller to the buyer which related to the goods," 2) "description of the goods," or 3) "sample or model" that "is part of the basis of the bargain." 13 PA. CONS. STAT. ANN. § 2313(a).

Additionally, the plaintiff must show that the express warranty was "directed at consumers in order to induce purchases of the product." Gross, 858 F. Supp.2d at 501. In other words, the consumer must show that he "read, heard, saw or knew of the advertisement containing the affirmation of facts or promise." Cipollone v. Liggett Group, Inc., 893 F.2d 541, 567 (3d Cir. 1990), rev'd on other grounds, 505 U.S. 503; see

² Defendants challenge plaintiff's strict liability claim to the extent it seeks to establish liability for a design defect. Plaintiff implicitly concedes that a recovery for design defect is preempted. Accordingly, defendants' motion will be granted as to this aspect of plaintiff's count for strict liability.

also Gross, 858 F. Supp.2d at 501; Parkinson v. Guidant Corp., 315 F. Supp.2d 741, 752 (W.D. Pa. 2004).

Additionally, once the buyer has accepted the goods, he must also show that he notified the defendant, or seller, within a reasonable amount of time about the defective condition. Vanalt Elec. Const. Inc. v. Selco Mfg. Corp., 233 Fed. Appx. 105, 108 (3d Cir. 2007). The plaintiff has the burden of proving that the notice required by 13 Pa. C.S. § 2607 was provided. Kee v. Zimmer, Inc., 871 F. Supp.2d 405, 410 (E.D. Pa. 2012) (citing Vanalt Elec. Const. Inc., 233 Fed. Appx. at 108-10). In relation to a motion to dismiss, a “plaintiff must ‘plead, at a minimum, . . . that [she] provided reasonable notification...to state a viable claim for recovery . . . or be barred from any remedy.’” Id. (quoting American Federation of State County and Municipal Employees v. Ortho-McNeil-Janssen Pharmaceuticals, Inc., 2010 WL 891150 *7 (E.D. Pa. 2010)).

Here, plaintiff lists numerous promises made by defendants through literature, advertisements, employees, and agents. These promises include that the Titan was designed to prevent auto-inflation, safe and effective for its intended use, and would restore confidence, relationships, and pleasure. The complaint avers that plaintiff relied on these representations in choosing the Titan to treat his dysfunction. These averments create a reasonable inference that he heard and understood these express warranties. The complaint further states that the implanted device deviated significantly and was the proximate cause of plaintiff’s injuries.

Plaintiff received the device at UPMC McGee through the assistance of Dr. Jaffee. By doing so it is reasonable to infer that Dr. Jaffee acted as an agent of defendants. After two and a half months, plaintiff notified Dr. Jaffee of the issues he was

experiencing. This state of affairs is sufficient to set forth a plausible showing of the required notice.

Dr. Jaffee suggested that plaintiff undergo another surgery to fix the problem. Plaintiff did undergo the recommended surgery, which created an opportunity for defendants to cure the problem. Although the defective pump was replaced and the new one is easier to compress, plaintiff still experiences auto-inflation, which defendants represented would not occur. The auto-inflation has caused and continues to cause plaintiff to experience pain, discomfort, and embarrassment. Hence, a breach has been identified. Therefore, plaintiff has averred sufficient facts to set forth a plausible claim for breach of express warranty.³

For the reasons set forth above, defendant's motion to dismiss will be granted in part and denied in part. An appropriate order will follow.

Date: September 18, 2018

s/David Stewart Cercone
David Stewart Cercone
Senior United States District Judge

cc: A. Michael Gianantonio, Esquire
Wendy West Feinstein, Esquire
Matthew H. Sepp, Esquire

(Via CM/ECF Electronic Mail)

³ Plaintiff agrees that his breach of implied warranty claim is preempted by the MDA. Accordingly, it will be dismissed as well.

